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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-------------------------------|-----------------------|---------------------|------------------|
| 10/567,453 | 07/18/2006 | Matthew David Osborne | BJS-620-412 | 4519 |
| 23117 NIXON & VAN | 7590 03/23/201 NDERHYE. PC | EXAMINER | | |
| 901 NORTH GLEBE ROAD, 11TH FLOOR | | | MARVICH, MARIA | |
| ARLINGTON, VA 22203 | | | ART UNIT | PAPER NUMBER |
| | | | 1633 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 03/23/2010 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief

| Application No. | Applicant(s) | |
|-----------------|----------------|--|
| 10/567,453 | OSBORNE ET AL. | |
| | | |
| Examiner | Art Unit | |

| The MAILING DATE of this communication appears on the cover sheet with the correspondence address |
|---|
| THE REPLY FILED 05 March 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. |
| 1. X The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this |
| application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time |
| periods: |
| a) The period for reply expiresmonths from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In |
| no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO |
| MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee |
| have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL |
| 2. The Notice of Appeal was filed on A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of |
| filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). AMENDMENTS |
| |
| 3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will <u>not</u> be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below); |
| (b) They raise the issue of new matter (see NOTE below); |
| (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or |
| (d) They present additional claims without canceling a corresponding number of finally rejected claims. |
| NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)). |
| 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). |
| 5. Applicant's reply has overcome the following rejection(s): |
| 6. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the |
| non-allowable claim(s). |
| 7. 🛛 For purposes of appeal, the proposed amendment(s): a) 🖾 will not be entered, or b) 🗌 will be entered and an explanation of |
| how the new or amended claims would be rejected is provided below or appended. |
| The status of the claim(s) is (or will be) as follows: |
| Claim(s) allowed: Claim(s) objected to: |
| Claim(s) rejected: <u>1-6,33-41 and 43-50</u> . |
| Claim(s) withdrawn from consideration: |
| AFFIDAVIT OR OTHER EVIDENCE |
| 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will <u>not</u> be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e). |
| 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will <u>not</u> be entered because the affidavit or other evidence failed to overcome <u>all</u> rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1). |
| 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. REQUEST FOR RECONSIDERATION/OTHER |
| 11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet. |
| 12. Note the attached Information <i>Disclosure Statement</i> (s). (PTO/SB/08) Paper No(s). |
| 13. \(\sum \) Other: Applicants request for acknowledgement on a signed 1449 that International Search Reports were considered is unclear. |
| The file shows two IDS that were considered, one filed 10/31/07 and a second filed 2/7/06, both of which contain listings of ISR. Both |
| ISR have been considered as demonstrated by the initials. Both IDS have been signed and returned to applicant. However, it is herein |
| confirmed that the ISR submissions have been considered. |
| /Maria B Marvich/ |
| , |

/Maria B Marvich/
Primary Examiner, Art Unit 1633

PTOL-303 (Rev. 08-06) Advisory Action Before the Filing of an Appeal Brief

Application No.

Part of Paper No. 20100317

Continuation of 3. NOTE: Applicants claims were previously drawn to a method of in vitro culture of a myleoma cell line comprising inoculating the cell in medium comprising iron or ferric ammonium citrate at concentrations of 0/064-3.1 mg/L or 0.4 to 20 mg/L. Applicants have thus amended the claims to create a new ratio of allowable iron or ferric ammonium citrate that requires new consideration of the art. Furthermore, the ratio recited in claim 1 leads to consideration of issues of new matter as well as 112 second. In the first instance, the specification does not disclose a range of 0.064 to 3.1.. As to the alter, the ratio ocludes the dependent claim 4 which falls outside of the range.

Continuation of 11. does NOT place the application in condition for allowance because: applicants have traversed the rejection under 35 USC 102 First, applicants argue that aside from falling outside of the new range for ferric ammonium citrate concentration does not demosntrate growth of the culture, which according to the specification is described by at least a doubling or preferably a tripling. However, the art teaches that in vitro cultured myeloma cells can have a doubling time of about 35 hours, hence within 48 hours, one would expect the cells to have doubled. As to Gorfien et al, applicants argue that the reference does not teach that the cells were grown in agitated suspension culture. Gorfien et al is directed to a cell culture medium for in vitro cultivation of cells in suspension. Specifically cited are NS/O myeloma cells. SPecifically, applicants teach that the taught media can be used specifically to culture these cells. Whiel Gorfien et al teach that "For suspension cultivation, cells are typically suspended in the present culture media and introduced into a culture vessel that facilitates cultivation of the cells in suspension, such as a spinner flask, perfusion apparatus, or bioreactor (see Freshney, R. I., Culture of Animal Cells: A Manual of Basic Technique, New York: Alan R. Liss, Inc., pp. 123-125 (1983)). Ideally, agitation of the media and the suspended cells will be minimized to avoid denaturation of media components and shearing of the cells during cultivation." It is noted that myeloma cells are grown in suspension and hence subjected to the media and culturing conditions taught as a whole by Gorfien et al. While Gorfien et al teach that agitation is kept to a minimum, there is no absence of agitation. Hence, as a whole Gorfien et al teach methods of culturing myeloma cells using media meeting the conditions of the isntant claims wherien the cells are grown i.e. in spinner flasks. Spinner flasks and other forms of culturing for suspension cells require that some agitation be present.